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IN THE
**SUPREME COURT OF THE UNITED STATES**

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PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA,

*Petitioner,*

v.

KEVIN CONCANNON, COMMISSIONER, MAINE DEPARTMENT OF HUMAN SERVICES, AND G. STEVEN ROWE, ATTORNEY GENERAL OF MAINE,

*Respondents.*

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**On Writ of Certiorari To The United States Court of Appeals For the First Circuit**

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# BRIEF *AMICI CURIAE* OF AARP, COMMUNITY CATALYST, FAMILIES USA AND THE MEDICARE RIGHTS CENTER IN SUPPORT OF RESPONDENTS

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# TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES ..... iii

STATEMENT OF INTEREST ..... 1

SUMMARY OF ARGUMENT ..... 4

ARGUMENT ..... 5

I. Introduction ..... 5

II. Neither the Letter nor the Intent of the Social Security Act Prohibit a State from Using Medicaid Prior Authorization to Achieve Prescription Drug Savings ..... 8

III. Maine Rx is Consistent with the Best Interest of Medicaid Recipients ..... 13

A. The Burden and Costs of Prescription Drugs Show Why So Many Maine Residents are in Need of Medical Assistance to Pay for Them, and Why it is in Medicaid's Interest to Assist Them ..... 14

IV. The Evidence that Individual Medicaid Beneficiaries will Suffer Actual Harm from Maine Rx's Reasonable Limitations on So-called First-Choice Rx Drugs is Insufficient to Support an Injunction ..... 18

A. Prior Authorization Does Not Inevitably Harm Patients ..... 19

1. Studies have shown that prior authorization can be implemented without resulting in adverse clinical outcomes ..... 19

2. Maine's existing prior authorization programs has not caused many problems with access to prescription medications .. 20

B. Physicians Will Not Abandon the Medical Welfare of their Patients in the Face of Prior Authorization Requirements ..... 21

1. Physicians are knowledgeable about prior authorization systems because they are extensively utilized in the health care system ..... 21

2. Drug promotion activities influence prescribing patterns ..... 24

CONCLUSION ..... 25



## TABLE OF AUTHORITIES

**Cases**

*Gade v. Nat'l Solid Wastes Mgmt. Ass'n*,
505 U.S. 88 (1992) ..... 8

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127 F.3d 993 (11th Cir. 1997) ..... 14

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413 U.S. 405 (1973) ..... 8

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249 F.3d 66 (1st Cir. 2001) ..... 7, 11, 13, 14, 19

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No. 02-10151, 2002 U.S. App. LEXIS 18487,
304 F.3d 1197 (11th Cir. Sept. 6, 2002) ..... 14

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No. 238862 (Mich. Ct. App. argued Sept. 5, 2002) ..... 2

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(D.C. Cir. Mar. 29, 2002) ..... 2, 6

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2000 Me. Legis. Serv. 786 ..... 2

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**ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT**

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## BRIEF *AMICI CURIAE* OF AARP, COMMUNITY CATALYST, FAMILIES USA AND THE MEDICARE RIGHTS CENTER IN SUPPORT OF RESPONDENTS

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## STATEMENTS OF INTEREST[1]

AARP is a national, nonprofit, nonpartisan organization for people 50 and over with more than 35 million members. More

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[1] No counsel for any party authored any portion of this brief. No persons other than amici curiae, their members, or their counsel have made a monetary contribution to the preparation and submission of this brief. The written consents of the parties have been filed with the Clerk of the Court pursuant to Supreme Court Rule 37.3.

than 192,000 members live in Maine. AARP supports state and national policy initiatives to broaden access to prescription drugs and to lower costs for medications. Because Medicare generally does not cover prescription drugs, AARP has been a strong supporter of state programs that broaden consumer access to affordable prescription drugs.

AARP in Maine advocated for passage of Maine's Act to Establish Fairer Pricing for Prescription Drugs (Maine Rx). Me. Rev. Stat. Ann. tit. 22, § 2681 (2001); 2000 Me. Legis. Serv. 786 (legislative history). AARP also supported the Pharmacy Drug Discount Program (PDDP) (known as Healthy Maine Prescriptions or HMP), a complementary program to Maine Rx which provides the Medicaid discount price to persons within 300% of the federal poverty threshold. AARP assisted in enrolling the more than 112,000 beneficiaries in Healthy Maine Prescriptions drug program. Thousands of Maine AARP members obtain medication through Healthy Maine Prescriptions, and many thousands more would participate in Maine Rx.

AARP has participated as *amicus curiae* in numerous recent cases involving state Medicaid prescription drug coverage, including filing briefs in support of Maine's Healthy Maine Prescriptions in *PhRMA v. Thompson*, 191 F. Supp.2d 48 (D.D.C. 2002), *appeal docketed*, No. 02-5110 (D.C. Cir. Mar. 29, 2002), and in support of Michigan in *PhRMA v. Michigan Dep't of Cmty. Health*, No. 238862 (Mich. Ct. App. argued Sept. 5, 2002). The latter case involves PhRMA's challenge to Michigan's attempt to contain drug costs in its Medicaid and other low-income prescription drug programs. AARP also is supporting numerous other states' pharmacy assistance programs providing coverage and/or reducing drug costs such as Oregon and Hawaii. Nationally, AARP is working for passage of a Medicare prescription drug benefit and AARP's "Check Up on Your Prescriptions" campaign encourages consumers to use medications wisely and safely, and to consider if lower cost generic drugs are appropriate for them.

Community Catalyst is a Boston-based national advocacy



organization that works in partnership with consumer and community groups around the country to promote health care justice. Community Catalyst seeks to strengthen the voice of consumers and communities wherever decisions shaping the future of our health system are being made. Community Catalyst provides a range of technical assistance services that includes policy analysis, legal assistance, strategic planning and community organizing support. Community Catalyst also builds coalitions among its constituencies on a range of issues, from hospital conversions and quality care to Medicaid expansions and prescription drug access.

Families USA is a national not-for-profit consumer advocacy organization that promotes policies to achieve high-quality, affordable health coverage for all Americans. Founded in 1982, Families USA has been and continues to be the leading voice for expanded health coverage to the uninsured and for low-income individuals and families. In support of this mission, Families USA has worked to strengthen the Medicaid and Medicare programs so that they are increasingly responsive to economically vulnerable individuals and families. Families USA also convenes and leads a broad coalition of consumer organizations that support and defend the continued viability of the Medicaid program. As an integral part of its mission, Families USA has developed and promoted policies that expand access to affordable prescription drugs for seniors and low-income families. Directly and through its support of health care advocacy groups nationwide, Families USA promotes programs designed to help individuals who lack prescription drug insurance to gain access to affordable medications. Families USA's interest in the Maine Rx Program directly stems from that program's goal of providing Maine residents with access to more affordable prescription drugs.

The Medicare Rights Center (MRC) is a national, consumer service organization that assists older and disabled Americans secure needed health care. MRC receives over 75,000 calls annually to its national and New York State consumer hotlines. Many MRC clients are struggling to pay for their health care, and MRC works with them to enroll in Medicaid and other assistance programs. By far, the most

common life-threatening health care need of MRC clients is their inability to afford drugs that their doctors prescribe. The Medicare Rights Center is leading a nation-wide campaign to bring the plight of older and disabled Americans who go without prescribed medication to the attention and conscience of the nation.

## SUMMARY OF ARGUMENT

*Amici Curiae*, AARP, Community Catalyst, Families USA, and the Medicare Rights Center join together in supporting Maine Rx, a state program seeking to improve access to prescription drugs for the people of Maine. The prices of prescription drugs place many drugs beyond the reach of many of the residents of Maine. Medicaid is a state-federal cooperative program designed to assist people to get medically necessary health care, and Congress has expressly granted states the authority to implement prescription drug prior authorization in their Medicaid programs. 42 U.S.C. § 1396r-8(d). Maine's use of prior authorization to induce manufacturers to provide discounts to all residents, not just persons eligible for the basic Medicaid benefits, does not conflict with the intent of Congress in establishing Medicaid. Maine Rx is consistent with the best interests of Medicaid recipients because, by expanding access to medicines for the general population, Maine Rx will keep more people healthier longer so they are less likely to become eligible for Medicaid benefits and further deplete the limited resources of the Medicaid program.

Based on the record in this case, PhRMA is unable to demonstrate that Medicaid recipients are likely to suffer irreparable harm as a result of prior authorization. First, the use of an effectively implemented, clinically sound prior authorization requirement does not inevitably harm patients. Second, Maine already has a Medicaid prior authorization program independent of Maine Rx which has shown few problems thus far. And third, there is little basis to believe that physicians will abandon the medical welfare of their patients in the face of a properly run prior authorization system. Prior authorization may even serve the salutary effect of counter-balancing the heavy pressure on doctors to prescribe a



particular drug because of promotion by the drug companies rather than its distinct therapeutic advantages.

Prescription drugs have become an increasingly important part of health care. But the dramatic increase in their costs means that many people simply cannot obtain the drugs to improve the quality of their lives and in some cases even prolong them. Maine recognizes that the health and welfare of its residents depend upon access to these medicines, and, through Maine Rx, believes it has found a way to lower the costs by connecting voluntary discounts to a reasonable limitation in the Medicaid program. The First Circuit decision should be affirmed, and Maine Rx should be implemented so that whatever discounts the manufacturers can be persuaded to offer can start benefitting the health of the people of Maine.

## ARGUM[illegible]

### I. Introduction

Maine is a low-income state, ranking thirty-sixth in the nation in per capita income.[2] The high and rising costs of prescription drugs has made it difficult for the State to publicly finance prescription drug programs. The availability of dramatically lower priced prescription medications in nearby Canada highlights the problem of unaffordable medications for Maine citizens and policy makers alike, and is a principal impetus for Maine's history of experimenting with programs aimed at increasing access to prescription medications for its citizens. Stephen Crystal et al., AARP Public Policy Institute, *Three States' Approaches to Pharmaceutical Assistance: A Guide for the Perplexed* 34 (2002); Tara Parker-Pope, *The Ins and Outs of Getting Drugs (The Legal Kind) From Across the Border*, Wall St. J., Oct. 22, 2002, at D1 (for example, showing

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[2] In 1999, Maine had a per capita money income of $19,533, compared with a national per capita income of $21,587. U.S. Census Bureau, *State and County Quick Facts: Maine*, *at* http://quickfacts.census.gov/qfd/states/23000.html (last visited Nov. 5, 2002).

Tamoxifen, a breast cancer drug, is $287.15 in the U.S. for 90 pills (20 mg), but $47.38 in Canada; Celebrex, an arthritis drug, is $133.25 in the U.S. for 100 pills (100mg) and $68.21 in Canada – prices are in U.S. dollars.)

In 1975, Maine established one of the country's first pharmacy assistance programs, Low Cost Drugs for the Elderly and Disabled Program (DEL or Low Cost Drug). Eligibility is restricted to persons 62 years-of-age and older and disabled persons age 19 or older, with both groups allowed incomes no more than 185 percent of poverty ($16,391 for one person in 2002). DEL is a subsidy plan so that these beneficiaries can obtain medications to treat specified illnesses. *See* Maine Dep't of Human Servs., *Prescription Drug Assistance: A Guide to Programs and Benefits* (2002), *available at* http://www.state.me.us/dhs/beas/medbook.htm [hereinafter Prescription Drug Assistance]. DEL is entirely financed through state funds. Crystal, *supra*, at 48.

Maine's standard Medicaid program, Maine Care, provides prescription drug benefits to eligible individuals, generally only to children and their families, the elderly and disabled who are extremely poor. As of March of 2002, the income eligibility requirements are a gross monthly income under $813 and assets under $2,000, or a couple with a gross monthly income under $1,095 and assets under $3,000. Prescription Drug Assistance, *supra*. Finding that access to prescription drugs was still a critical problem for the rest of the people of Maine, the State recently established two pharmacy discount programs, Maine Rx and Healthy Maine Prescriptions. Healthy Maine is a Medicaid waiver program, established under section 1115 of the Social Security Act, which allows the state to conduct experimental projects which further the objectives of the Medicaid program. Me. Rev. Stat. Ann. tit. 22, § 258 (2001). Healthy Maine Prescriptions provides the Medicaid discount price to any Maine resident whose income is within 300% of the federal poverty threshold, and generally provides an average of 25% savings off retail drug prices. Prescription Drug Assistance, *supra*. Healthy Maine is also being challenged by PhRMA in *PhRMA v. Thompson, supra*.



Maine Rx is an innovative state program aimed at remedying the serious financial barriers to access for prescription drugs faced by many Maine residents who still have a problem affording medications yet whose incomes are not low enough to qualify for other prescription drug assistance programs. Maine Rx helps people obtain needed prescription drugs, drugs they do without when costs are too great.[3] Lowering the cost of drugs is one way to increase access so that consumers will fill the prescriptions their doctors have determined they need. Judge Keeton recognized that "many and probably most citizens of Maine who have a need for pharmacy products would not have adequate resources and practical means to get the pharmacy products they need absent the Maine Rx Program." *PhRMA v. Concannon*, 249 F.3d 66, 97 (1st Cir. 2001)(Keeton, J., concurring).

Maine Rx uses a prior authorization mechanism in its Medicaid program to encourage drug manufacturers to negotiate price rebates with Maine so that the State can lower the cost of drugs for all the people of the state. PhRMA argues that Maine Rx's use of prior authorization in its Medicaid program to leverage manufacturer participation in Maine Rx violates the Supremacy Clause of the United States Constitution because it conflicts with the Social Security Act, and that Maine Rx's rebate provision conflicts with the Commerce Clause. This brief will address only the question of whether Maine Rx's

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[3] A recent survey of eight states reports that nearly one quarter of all seniors said that they did not fill a prescription because it was too expensive or skipped doses of their medications to make them last longer. Even patients with severe and chronic conditions like heart disease and diabetes often go without medication because of costs. Kaiser Foundation et al., *Seniors and Prescription Drugs, Findings From a Survey of Seniors in Eight States* (July 2002). In a March 2002 national survey of Americans aged 45 or older, more than one in five (22%) reported they did not fill at least one prescription prescribed by their doctor during the last two years, with the cost of the drug being the main reason people cited for not getting their prescription filled. AARP, *Prescription Drug Use Among Persons Age 45+* 24-25 (June 2002). Of particular concern is that the proportion of people who say cost was a main reason for not getting a prescription is rising, up from 13% during a 1986 survey to 32% in 2002. *Id.* at 72.

attempt to bring down the cost of prescription drugs for all its people violates the Supremacy Clause.

## II. Neither the Letter nor the Intent of the Social Security Act Prohibit a State from Using Medicaid Prior Authorization to Achieve Prescription Drug Savings.

Under the Supremacy Clause, a federal law may expressly or impliedly preempt state law. *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 98 (1992). The beginning assumption is that "the historic police powers of the States [are] not to be superseded by the Federal Act unless that [is] the clear and manifest purpose of Congress." *Rice v. Sante Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)(citations omitted). This is especially true with co-operative federalism programs such as Medicaid. Where coordinate state and federal efforts exist within a complementary framework, and in the pursuit of common purposes, the case for federal preemption becomes a less persuasive one. *N.Y. Dep't of Soc. Servs. v. Dublino*, 413 U.S. 405 (1973).

PhRMA argues that Maine's use of prior authorization in its Medicaid program impliedly conflicts with the Social Security Act despite the Act's expressed authorization of state prior authorization programs for any pharmaceutical benefit it provides. 42 U.S.C. § 1396r-8(d)("A State may subject to prior authorization any covered outpatient drug.") Their argument stretches implied conflict preemption far beyond any precedent of this Court. PhRMA cites no court decision holding anything analogous, other than the district court decision reversed by the First Circuit. Precedent aside, PhRMA argues that Maine Rx must be struck down even before it is implemented because prior authorization necessarily creates such a burden on Medicaid beneficiaries that it conflicts with the object and purpose of Congress in enacting Medicaid.

Far from conflicting with congressional intent, Maine Rx is consistent with long-standing Congressional concern with the costs of prescription drugs and the corresponding burden on publicly financed health care coverage. In 1990, Congress



recognized that it had to do something about the costs of prescription drug to the Medicaid program. Medicaid is one of the largest purchasers of drug manufacturers' products -- if the not the largest -- yet the manufacturers were routinely charging Medicaid more than what they charged other large drug purchasers. H.R. Rep. No. 101-881, at 96 (1990), *reprinted in* 1990 U.S.C.C.A.N. 2017, 2108. Congress established a rebate requirement for manufacturers who participate in Medicaid, allowing state Medicaid programs to use their positions as a huge purchaser of the manufacturers' products to require manufacturers to reduce their profits.
42 U.S.C. § 1396r-8 (a)(1)(2002)("In order for payment to be available . . . [under Medicaid] the manufacturer must have entered into and have in effect a rebate agreement . . . with the Secretary, on behalf of States.") The goal was to allow Medicaid programs to reduce the prices of prescription drugs.

At the same time, Congress permitted individual state programs to choose certain other methods to control costs of providing prescription drugs. For example, states can restrict or exclude entire classes of drugs, limit quantities, or impose prior authorization as a condition of coverage. *See* 42 U.S.C. § 1396r-8(d)("Limitations on coverage of drugs.") Congress made sure that when a state chooses to require prior authorization, it must do so in a fashion that does not harm Medicaid beneficiaries. State programs must provide fast responses to authorization requests and dispense a three day supply of the requested drug in an emergency situation.
42 U.S.C. § 1396r-8(d)(1)(A) and (d)(5).[4]

Much has been made of the fact that Maine is attempting to use Medicaid prior authorization to assist all its people with

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[4] Maine must also comply with other Medicaid requirements designed to assure beneficiaries efficiently receive good quality health care, such as promptly furnishing health care, 42 U.S.C. §1396a(a)(8); timely providing the beneficiary with notice and hearing rights upon reductions, terminations and denial of care, 42 U.S.C § 1396a(a)(3); and assuring that care and services are available to Medicaid beneficiaries at least to the extent that those services are available to the general population, 42 U.S.C. § 1396a(a)(30)(A).

drug c sts, not just the poorest of the poor who are eligible for all of the state's Medicaid benefits. Because Maine is using the authority given it by Congress to use prior authorization in its Medicaid program to help those who are beyond the financial eligibility limits of basic Medicaid, both PhRMA and the Solicitor General argue it does not serve the interests of the Medicaid program. (Pet'r Br. at 26; United States Br. Supp. Reversal at 10.)

The purpose of the Medicaid program is to provide health care to those in need, therefore, Maine's attempt to expand access to health care does not contradict Congressional intent. Maine Rx is entirely consistent with the Medicaid provisions of the Social Security Act; nothing in the Act prohibits either pharmacy discount programs, or states from expanding Medicaid coverage. Providing pharmacy discounts serves Medicaid's objective to furnish medical assistance on behalf of families with dependant children, and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services. 42 U.S.C. § 1396 (2002). Maine Rx simply increases the number of persons eligible to receive the benefit of a discount obtained through the State's efforts to furnish medical assistance -- in this case, access to pharmaceuticals.

As a practical matter, the enrollees in Maine Rx most likely to benefit from the program are the population most sensitive to the high costs of prescription medications-- lower income persons, without prescription drug coverage insurance or the means to purchase prescription drugs, such as the 40% of Medicare beneficiaries with annual incomes below $10,000 who lacked prescription drug coverage in the fall of 1999. David Gross, AARP Public Policy Institute, *Medicare Beneficiaries and Prescription Drugs: Costs and Coverage* (2002), *available at* http://reasearch.aarp.org/health/dd77_rx.html. The Maine Legislature passed Maine Rx "to enable the State to act as a pharmacy benefit manager in order to make prescription drugs more affordable for qualified Maine residents, thereby increasing the overall health of Maine residents, promoting healthy communities and protecting the public health and welfare." Me. Rev. Stat. Ann. tit. 22,



§ 2681 (2001). The First Circuit recognized that this goal was consistent with Medicaid: "The Maine Rx Program will potentially provide prescription drugs to Maine citizens who could not otherwise afford them." *Concannon*, 249 F.3d at 84.

Medicaid benefits are not restricted to a static population subject to a uniform set of eligibility requirements, such as those persons who meet the low income and resources standards of Supplemental Security Income (SSI).[5] There are many state programs which utilize the Medicaid program to expand health care assistance beyond the group it traditionally covers. While state Medicaid programs must provide coverage to individuals receiving cash assistance through the Temporary Assistance for Needy Families (formerly AFDC) or SSI, states can elect to provide Medicaid coverage to "medically needy" individuals whose incomes exceed state established income levels. 42 U.S.C § 1396a(a)(10)(C) (2002). Maine has a medically needy program under which children, elderly, or disabled with very high medical bills can become eligible for services by spending enough of their income on health care to meet a state established income limit.[6] In addition, as of 1989, States participating in the Medicaid program were required to pay Medicare premiums and cost sharing amounts for certain low income Medicare beneficiaries whose income exceeded SSI eligibility levels. 42 U.S.C. §§1396a(a)(10)(E)(i); 1396d(p) (2002).

States can also use a variety of mechanisms such as waivers, like Maine has done with the Healthy Maine program discussed earlier, to cover broader populations and provide

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[5] In 2002, in order to be eligible for SSI, a single person could earn no more than $780 per month, with a $2,000 resources limitation. U.S. Soc. Sec. Admin., *Fact Sheet: Social Security, available at* http://www.ssa.gov/pressoffice/colafacts2003.htm (last visited Nov. 5, 2002).

[6] The provision of the Maine Medicaid program, known as MaineCare, that establishes the medically needy category of eligibility can be found at CODE ME. R. §10-144-332.1100 (2002). The income requirements are covered in § 10-144-332.2450.

additional services. *See* Medicaid home and community based waivers (§1915(c) of the Social Security Act codified at 42 U.S.C. § 1396n (2002)); "Freedom of choice" waivers (§ 1915(b)of the Social Security Act codified at 42 U.S.C. § 1396n (2002)) and "research and demonstration" waivers (§ 1115 of the Social Security Act codified at 42 U.S.C. § 1315 (2002). Under these provisions, states can request the Secretary of Health and Human Services waive certain federal requirements in the general Medicaid program so that they can provide health care benefits which may provide different services, use a more generous financial eligibility criteria, or provide benefits to a particular group which are not provided to all Medicaid beneficiaries. *See, i.e.,* 42 U.S.C. §1396a(a)(10)(B) (2002) (relating to comparability of service requirements). "Waivers are intended to provide flexibility needed to enable States to try new or different approaches to the efficient or cost effective delivery of health care services, or to adapt their programs to the special needs of particular areas or groups of recipients." 42 C.F.R. §430.25(b) (2002).

Extending care to persons in need beyond just the poorest of the poor is a long-standing purpose of the Medicaid program. There are many more examples of this, but a recent study summarizing the Medicaid enrollment data from the states demonstrates "that Medicaid continues to evolve from a welfare-based program to a more traditional health insurance program." Kaiser Comm'n on Medicaid and the Uninsured, *Report on Medicaid Enrollment in 50 States: December 2001 Data Update* (Oct. 2002) *available at* http://www.kff.content/2002/4067/4067.pdf.

Maine Rx allows the Commissioner, if he is successful in his negotiations with drug manufacturers, to provide a discount for Maine residents who need to purchase prescription drugs. Such discounts help those whose income is above current eligibility levels for all Medicaid's benefits, but it also serves the interest of the Maine's Medicaid program as a whole, as is further described below. Lowering the cost of the prescriptions means that more people can afford health-sustaining medications and prevents their health from deteriorating to the point that those persons become financially eligible for



Medicaid benefits. This acts to preserve limited Medicaid funds for those already eligible. See *Concannon*, 249 F.3d at 76-77 (citing evidence on the limited record before it showing Maine Rx may reduce Medicaid expenditures). Moreover, the Medicaid program itself will save money when clinically appropriate, less expensive drugs are prescribed over more expensive drugs with no therapeutic advantage through an effectively implemented prior authorization program.[7]

## III. Maine Rx is Consistent with the Best Interests of Medicaid Recipients.

The Medicaid statute directs states to consider the "best interests" of Medicaid beneficiaries. State plans must "assure that eligibility for care and services under the plan will be determined, and such care and services will be provided, in a manner consistent with simplicity of administration and the best

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[7] Maine should thoughtfully and effectively implement its prior authorization program because all Medicaid recipients must have efficient access to all medically necessary prescription drugs. Maine Rx has not yet been implemented, but Commissioner Concannon has attested that the Maine Department of Human Services will assure that Medicaid beneficiaries receive all medically necessary medications. *Concannon*, 249 F.3d at 76. Given Maine's history of attempting to expand access to prescription drugs, see discussion *supra* at 5-6, there is no reason to doubt Maine official's assertions. Moreover, Maine provides protection in the prior authorization program beyond federal requirements. While federal law only requires that a 72-hour supply of medicine be dispensed in an emergency situation, Maine is more generous, authorizing the pharmacist to provide a 96-hour supply of the prescribed drug whenever the Department is unable to promptly respond to the prior authorization request. *See* Maine Dep't of Human Servs., MaineCare Benefits Manual, 10-144, ch. 101 § 80.07-3, *available at* http://www.state.me.us/sos/cec/rcn/apa/10/ch101.htm. Commissioner Concannon has also given pharmacists the ability to "provide a one-time fill of a 34-day supply prior to establishing medical necessity via the prior authorization process." (Letter from Kevin W. Concannon to Ronald Preston, Associate Regional Administrator, Division of Medicaid and State Operations of Oct. 31, 2002, at 3.) *See* Lodging of *Amicus Curiae* Maine Citizen Leadership Fund.

interests of the recipients." 42 U.S.C. § 1396a(a)(19) (2002). PhRMA argues that this provision is violated because some unidentified and unknown number of people may encounter obstacles in receiving "first-choice" prescription drugs because of a prior authorization requirement. (Pet'r Br. at 17.) However, both the First and Eleventh Circuits have considered the best interests language and determined it to be directed at the state's Medicaid program as a whole, not to its individual recipients.

The First Circuit decided that Maine Rx furthered Medicaid purposes because making prescription drugs more accessible to the uninsured and underinsured may reduce Maine's Medicaid expenditures by keeping people healthier longer so they do not ultimately end up using more costly Medicaid services. *Concannon*, 249 F.3d at 76. The Eleventh Circuit recently upheld a prior authorization program in Florida's Medicaid program, concluding that the Florida law "operates to drive down the cost of prescription drugs under the Medicaid program by providing drug manufacturers with strong economic incentives to offer the state supplemental rebate.... By stretching its Medicaid dollars, the Florida law has the potential for providing more and better medical services to its target population." *PhRMA v. Meadows*, No. 02-10151, 2002 U.S. App. LEXIS 18487, at *31-31, 304 F.3d 1197 (11th Cir. Sept. 6, 2002). *Cf. Harris v. James*, 127 F.3d 993, 1010 (11th Cir. 1997) (finding §1396a(A)(19) imposes a generalized duty on the States and is insufficiently specific to confer any particular rights on a plaintiff, and citing other similar cases). Protecting the program as a whole is the only way to ultimately protect the program for the individual, particularly when states face budget crises and are forced to cut eligibility and services as described below.

**A. The Burden and Costs of Prescription Drugs Show Why So Many Maine Residents are in Need of Medical Assistance to Pay for Them, and Why it is in Medicaid's Interest to Assist Them.**

Prescription drug costs are becoming the major strain on publicly funded insurance programs as drug costs are the fastest



growing component of health care, rising 15% or more per year over the past several years. Nat'l Inst. for Health Care Mgmt. Research & Educ. Found., *Prescription Drug Expenditures in 2001: Another Year of Escalating Costs* 2 (2002), *available at* http://www.nihcm.org/spending2001.pdf. A key factor in rising drug costs is rising drug prices. According to the National Institute for Health Care Management, roughly one-third of the increase in drug costs is attributable to rising drug prices. *Id.* at 3. Prices have a disproportionate impact on those individuals who lack coverage for prescription drugs. In fact, in calendar year 2001, the prices of the 50 drugs most commonly prescribed for seniors, increased three times the rate of inflation. *See* Families USA, *Bitter Pill: The Rising Prices of Prescription Drugs for Older Americans* (June 2002), *available at* http://www.familiesusa.org/BitterPillreport.pdf. These price increases are reflective of a long standing trend of rising drug prices. This same study found that prices for the 50 drugs most commonly prescribed for seniors, increased at rates far faster than inflation over the last 5 years and the last 10 years. *Id.* One of the main goals of the Maine Rx Program is to moderate these price increases and ameliorate the impact of these rising prices for those individuals who lack coverage.

Not only are rising prescription drug costs a strain on individuals, they are also placing a tremendous strain on publicly funded programs such as Medicaid. The Medicaid program is a vitally important source of drug coverage for low-income disadvantaged people nationwide, paying for approximately 14 percent of prescriptions written in the U.S. in 2000. *See* Brian K. Bruen, Kaiser Comm'n on Medicaid and the Uninsured, *States Strive to Limit Medicaid Expenditures for Prescribed Drugs* 2 (Feb. 2002), *available at* http://www.kff.org/content/2002/20020213/4030.pdf. Medicaid spent $16.6 billion of federal and state funds on outpatient drugs in 2000; that figure does not include what was spent in Medicaid managed care plans, or hospitals or other settings where drugs are included in the total payment for services. *Id.* at 3. Older persons and persons with disabilities accounted for 80 percent of Medicaid drug spending in 1998. Kaiser Comm'n on Medicaid and the Uninsured, *Medicaid and Prescription Drugs: An Overview* (Oct. 2000), *at* http://www.kff.org/

content/2001/1609/ 1609.pdf.

Medicaid programs are under great pressure to reduce coverage and services due to soaring costs and budget pressures.[8] In fiscal year 2002, state spending on Medicaid increased 11 percent. *See* Kaiser Survey, *supra* note 8, at 15. Medicaid programs are stressed not only by the rising costs for current beneficiaries, but also by the increasing number of persons being driven into poverty and therefore becoming eligible for Medicaid. The poverty rate in 2001 rose for the first time since 1991-1992, reaching 32.9 million persons or 11.7% of the population, up from 11.3% in 2000. Bernadette

[8] The vast majority of states are facing significant budget shortfalls. *See* Kaiser Comm'n on Medicaid and the Uninsured, *State Budgets Under Stress: How are States Planning to Reduce the Growth in Medicaid Costs?* (July 2002) [hereinafter Kaiser State Budget Report]; Nat'l Ass'n of State Budget Officers, *NASBO Analysis: Medicaid to Stress State Budgets Severely in Fiscal 2003* (March 15, 2002). In an effort to control Medicaid expenditures, states are reducing benefits and restricting Medicaid eligibility criteria, cost containment strategies that eliminate health care for Medicaid beneficiaries. *See* Kaiser State Budget Report, *supra*, at 23-5; Amy Goldstein, *States' Budget Woes Fuel Medicaid Cuts: Poor Lose Coverage and Services*, Wash. Post, Oct. 11, 2002, at A01. Missouri, for example, cut over 30,000 people from Medicaid by lowering the threshold at which parents become eligible. Vernon Smith, PhD, et al., Kaiser Comm'n on Medicaid and the Uninsured, *Medicaid Spending Growth: Results From a 2002 Survey* 25 (Sept. 2002), *available at* http://www.kff.org/content/2002/4064/4064.pdf [hereinafter Kaiser Survey]. Massachusetts is eliminating coverage for approximately 50,000 long-term unemployed individuals and Nebraska is enacting eligibility cuts that will cause 12% of the state's total Medicaid enrollees to lose eligibility. *Id.* In fact, 18 states are planning eligibility cuts or restrictions for 2003, up from eight states restricting eligibility in 2002. *Id.* Meanwhile, the number of states making Medicaid benefit reductions is increasing. After nine states reduced benefits in fiscal year 2002, 15 states have passed benefit reductions for 2003. *Id.* at 24. Thirteen states have reduced long term care; cuts include shutting down nursing homes and instituting new reimbursement methodologies. *Id.* States are also reducing benefits through copays, increased cost sharing, managed care expansions, and increased disease management programs. *Id.*



D. Proctor & Joseph Dallaker, U.S. Census Bureau, P60-219, *Poverty in the United States: 2001* 2 (Sept. 2002), *available at* http://www.census.gov/prod/2002pubs/p60-219.pdf.[9] The number of uninsured also rose in 2001 to 41.2 million people or 14.6% of the population up from 14.2 % in 2000. Robert J. Mills, U.S. Census Bureau, P60-220, *Current Population Reports, Health Insurance Coverage: 2001* 2 (Sept. 2002), *available at* http://www.census.gov/prod/2002pubs/p60-220.pdf. Concomitant with the increase in poverty and decrease in insurance coverage, is an increase in the number of persons on Medicaid. The percentage of people covered by Medicaid rose from 10.6 % in 2000 to 11.2 % in 2001. *Id.*

Medicaid budgets simply cannot sustain prescription drug prices rising at current rates, and in many states the result has been, and will continue to be, program cuts. The objectives of the Medicaid Act are served when states reduce prescription drug costs expanding access, not when they are forced to cut benefits and eligibility for Medicaid programs. Limiting access for effective drugs puts frail, low-income, elderly patients at increased risk of institutionalization in nursing homes and may actually increase Medicaid costs. S.B. Soumerai et al., *Effects of Medicaid Drug-Payment Limits on Admission to Hospitals and Nursing Homes*, 325 New Eng. J. Med. 1072 (1991). Most of these patients once admitted to nursing homes never returned to the community. *Id.* Other research by these authors found that limits on coverage for the costs of mental health medication resulted in sharp increases in the use of emergency mental health services and partial hospitalizations. S.B. Soumerai et al., *Effects of Limiting Medicaid Drug-Reimbursement Benefits on the Use of Psychotropic Agents and Acute Mental Health Services By Patients With Schizophrenia*, 331 New Eng. J. Med. 650 (1994). The authors concluded that in addition to increasing the use of acute mental health services

[9] The poverty threshold is $8,494 for a single person 65 years of age and older and $9,214 for a person under 65. *Id.* at 5. Maine's household median income fell 5.9% in 2000-2001 from the previous two-year period. Carmen DeNavas-Walt & Robert W. Cleveland, U.S. Census Bureau, P60-218, *Money Income in the United States: 2001* 11 (Sept. 2002), *available at* http://www.census.gov/prod/2002pubs/p60-218.pdf.

among low-income patients with chronic mental illnesses, limits on coverage for the costs of prescription drugs also increased costs to the government and caused pain and suffering on the part of the patients. *Id.* Therefore, increasing access to effective prescription drugs -- both within the Medicaid program and the general population -- will save money for the Medicaid program as a whole.

States reported that the most significant factor contributing to higher Medicaid spending was the increasing costs of prescription drugs. Bruen, *supra*, at 15. Forty-four states cited prescription drugs among the three most significant factors driving Medicaid costs, with 25 states ranking prescription drugs as the single most significant factor behind increased Medicaid spending. *Id.* at 16. With the costs of drugs being so high, this is an area where States are looking to cut. The survey of Medicaid officials in all 50 states and the District of Columbia revealed that, in fiscal year 2003, 40 states plan to implement prescription drug cost controls, up from 32 states in FY 2002. *Id.* at 4. Cost containment controls such as prior authorization requirements are one way states are contending with increasing Medicaid costs. In fact, in fiscal year 2003, 23 state Medicaid programs plan to place more prescription drugs under prior authorization. *Id.* at 23. Maine can, and already is, doing the same. When Maine, acting as a pharmacy benefits manager for the entire population, leverages its buying power in the Medicaid program to bring down the costs for everyone, thereby facilitating greater access to medicines, its entire population is healthier and therefore less likely to incur the illnesses that will require them to need the resources of an already overburdened Medicaid program.

## IV. The Evidence that Individual Medicaid Beneficiaries will Suffer Actual Harm from Maine Rx's Reasonable Limitations on So-Called First-Choice Rx Drugs is Insufficient to Support an Injunction.

PhRMA argues that creating an obstacle to "first-choice drugs" constitutes a harm to Medicaid beneficiaries sufficient to warrant an injunction against the implementation of Maine Rx. (Pet'r Br. at 5.) But that argument fails because PhRMA is



unable to show that the obstacle of prior authorization will result in irreparable harm to Medicaid beneficiaries. "A facial challenge to a legislative act is of course the most difficult challenge to mount successfully since the challenger must establish that no set of circumstance exist under which the act would be valid." *United States v. Salerno*, 482 U.S. 739, 745 (1987). "The existence of a hypothetical or potential conflict is insufficient to warrant the preemption of the state statute." *Rice v. Norman Williams Co.*, 458 U.S. 654, 659 (1982). The First Circuit correctly concluded that dueling affidavits and other materials in the record fell short of establishing that the Act will inflict inevitable or even probable harm on Medicaid patients. *Concannon*, 249 F.3d at 77-78.[10]

PhRMA's argument presupposes that whenever so-called first-choice drugs face the need for prior authorization beneficiaries will be harmed, and further assumes that physicians will fail to advocate for clinically appropriate drugs for their patients. Prior authorization does not inevitably or necessarily harm Medicaid beneficiaries, and doctors can work with an effectively administered prior authorization program to assure Medicaid beneficiaries receive medically appropriate drugs.

### A. Prior Authorization Does Not Inevitably Harm Patients.

#### 1. Studies have shown that prior authorization can be implemented without resulting in adverse clinical outcomes.

A large study in an urban teaching hospital found no adverse effects on clinical outcomes as a result of prior authorization requirements for selected drugs. A. Clinton

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[10] PhRMA argues that there is actual harm to Medicaid recipients despite the fact that Maine Rx has never been implemented by citing the dispensing limitation (four drugs) in the Florida prior authorization program, and arguing that problems there demonstrates harm to Maine Medicaid beneficiaries. Maine Rx does not contain a dispensing limitation– a feature that apparently does cause problems with access to drugs.

White, Jr., et al., *Effects of Requiring Prior Authorization for Selected Antimicrobials: Expenditures, Susceptibilities, and Clinical Outcomes,* 25 Clinical Infectious Diseases 230 (1997) (concluding that requiring prior authorization of selected antimicrobial drugs can decrease expenditures and improve susceptibilities to antibiotics without compromising patient outcomes or length of hospital stay.) A study of the Tennessee Medicaid program's implementation of a prior authorization requirement for non-generic nonsteroidal anti-inflammatory drugs found a 53% decrease in expenditures for NSAID prescriptions, with no concomitant increase in Medicaid expenditure for other medical care. Walter E. Smalley, M.D., et al., *Effect of Prior-Authorization Requirement on the Use of Nonsteriodal Anti-inflammatory Drugs by Medicaid Patients*, 332 New Eng. J. of Med. 1612 (1995).

The studies do not establish by any means that prior authorization can never cause problems for a particular patient, but do show that prior authorization programs do not inevitably or even probably result in harmful clinical outcomes.

**2. Maine's existing prior authorization program has not caused many problems with access to prescription medications.**

Since 2001, Maine has subjected some prescription drugs to prior authorization under the authority of 42 U.S.C. § 1396r-8(d) and has data on its implementation. During the most recently analyzed period, January to September 2002, Maine filled more than 3.3 million prescriptions through the Medicaid program. Kevin W. Concannon, *Perspectives on Promoting the Appropriate Use of Pharmaceuticals, at* http://www.oregonrx.org/Ogrxpdf/Governor's%20Conference%20presentations%20PDF/Commisioner_OREGON_Revision_20021001.pdf (last visited Nov. 5, 2002). During that period, Maine's Medicaid program had 31,169 requests for prior authorization, or .94 percent of the total number of prescriptions. Ninety-three percent were approved, with an average determination time of 2.08 hours. *Id.* Ninety one percent of the requests were determined within 24 hours. *Id.* Less than one tenth of one percent, or 2,182, of



the total Medicaid prescriptions were unapproved, and a number were unapproved because of insufficient data for determinations such as incorrect NDC codes, ineligible patients, and absent or insufficient clinical support. *Id.* A grievance or fair hearing process should ensure that the remaining disputes are resolved in a manner that ensures beneficiaries obtain medically necessary drugs.

**B. Physicians Will Not Abandon the Medical Welfare of their Patients in the Face of Prior Authorization Requirements.**

**1. Physicians are knowledgeable about prior authorization systems because they are extensively utilized in the health care system.**

Because doctors are familiar with prior authorization programs, Maine's expansion of prior authorization in its Medicaid program will not inexorably lead to harm for its Medicaid beneficiaries. "The percentage of employers using prior authorization programs to manage access to specific drugs has increased every year since PBMI [Pharmacy Benefit Management Institute] first asked about its use. In 1996, 43% of employers used prior authorization programs; in 2000, that number increased to 77%." Inst. Mgmt. & Admin., *In Perspective*, Managing Benefits Plans 7 (Mar. 2002). Eighty-two percent of HMO plans used prior drug authorization in 2000. Joseph Eichenholz, *Trends in Managed Care Pharmacy: Responding to Changing Environments*, 8 J. Managed Care Pharmacy 104 (Mar./Apr. 2002).

As PhRMA phrases it, the law "forc[es] the physician to choose between a first-choice drug that requires prior authorization and second-choice, possibly less effective drug, that does not." (Pet'r Br. at 15.) That supposition does not rise to the level of demonstrating an inevitable conflict with the best interests of Medicaid recipients. For any given Medicaid beneficiary, no one knows what would be a "first-choice drug." The first choice may be one which does not require prior authorization. And if a first choice drug does require prior approval, if it is superior for that patient, the physician can

request it. If a drug requiring prior authorization is first-choice for any reason other than for that particular patient it is medically superior, then substitution will not harm the Medicaid beneficiary.

Substitution itself is not necessarily harmful, although for any particular patient there may be clinical reasons a specific drug is better. But with respect to the medical need for a specific drug, perception may not be reality. For example, the Food and Drug Administration (FDA) recognizes that simply because generic drugs cost less money, many people falsely perceive them as less effective than more expensive name brand medications. FDA, *FDA Ensures Equivalence of Generic Drugs, at* http://www.fda.gov/cder/about/whatwedo/testtube-17.pdf ("Generic drugs contain exactly the same active ingredients as the brand-name drug and are just as safe and effective.") The reality is that if there is a generic available for a name brand medication, it must be bio equivalent in that it performs in the same manner. *Id.*

A pharmacist sums up generic switching for brand names:

> Making unnecessary switches for economic motives only that end up causing adverse effects for patients or actually cost the health care system more in other costs because of greater use of system resources elsewhere . . . should be avoided in every instance. It would be foolish and harmful to argue against real cases where patients are hurt by switches. But, in reality, few cases have been published suggesting problems despite the millions of prescriptions filled with generic equivalents annually.

John E. Murphy, PharmD, *Generic Substitution and Optimal Patient Care*, 159 Archives Internal Med. 429 (1999).

Maine's prior authorization requirement will undoubtedly force the doctors to make informed prescription choices among



therapeutically equivalent drugs.[11] Savings are achieved when doctors determine that there is no medical reason to prescribe a drug requiring preauthorization. These are the kinds of clinical judgments entrusted to physicians every day. There is no basis on this record to believe that physicians in Maine will prescribe less effective therapies for their patients because Maine requires them to think about which drugs they are prescribing. Educating medical providers about how to obtain necessary medications and ensuring an efficient state administrative process are issues that go to the implementation of a prior authorization program, not grounds for concluding that it is necessarily against the best interests of patients.

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[11] The House Report accompanying H.R. 5835, the legislation which eventually became the prescription drug prior authorization provision of the Social Security Act, recognized the tension between prior authorization and physician discretion, stating:

> As under current law, States would have the option of imposing prior authorization requirements with respect to covered prescription drugs in order to safeguard against unnecessary utilization and assure that payments are consistent with efficiency, economy, and quality of care. However, the Committee does not intend that States establish or implement prior authorization controls that have the effect of preventing competent physicians from prescribing in accordance with their medical judgment. This would defeat the intent of the Committee bill in prohibiting States from excluding coverage of prescription drugs of manufacturers with agreements -- i.e., assuring access by Medical beneficiaries to prescription drugs where medically necessary.

H.R. Rep. 101-881 at 98 (1990), *reprinted in* 1990 U.S.C.C.A.N. 2017, 2110. Congress clearly understood that prior authorization has the potential to limit coverage, but that as long as beneficiaries get medically necessary drugs, it is an acceptable limitation.

**2. Drug promotion activities influence prescribing patterns.**

Indeed, prior authorization requirements may serve to counter-balance the heavy pressure put on physicians to prescribe a particular drug, not because of its therapeutic advantages, but rather because of promotion by the drug companies. While the link between drug promotion and prescriber behavior is not yet well understood, one survey found that 71 percent of family physicians believe that direct-to-consumer ("DTC") advertising pressures physicians into prescribing drugs that they would not ordinarily prescribe. Martin S. Lipsky, MD, & Christine A. Taylor, *The Opinions and Experiences of Family Physicians Regarding Direct-to-Consumer Advertising,* 45 J. Fam. Pract. 495, 497 (1997). There is at least a suggestion that DTC campaigns may result in increased prescribing for certain drugs. Promotional spending directed at consumers has increased significantly. Richard Frank, PhD, et al., Kaiser Family Foundation, *Trends in Direct-to-Consumer Advertising of Prescription Drugs*, (Feb. 2002)(finding a nine-fold increase in DTC advertising between 1994 and 2000). There "is strong circumstantial evidence that sales of the three prescription oral antihistamine drugs Claritin, Allegra and Zyrtec – all approved in the early to mid 1990s – have been substantially boosted by heavy DTC ad campaigns from 1998 to 2000." Steven D. Findlay, Nat'l Inst. for Health Care Mgmt. Research & Educ. Found., *DTC Advertising: Is it Helping or Hurting?* 3 (Sept. 10, 2002)(statement before the Federal Trade Commission health care workshop). Unfortunately, prescriptions driven by patient demand or based on promotional information may not always be the most appropriate choice; "previous findings [demonstrate] that demand by patients is the most common reason offered by physicians for inappropriate prescribing." Meredith B. Rosenthal, PhD, et. al., *Promotion of Prescription Drugs to Consumers* 346 N. Eng. J. Med. 498, 503 (2002)(citing Schwartz, et al., *Physician Motivations for Nonscientific Drug Prescribing*, 28 Soc. Sci. Med. 577-82 (1989)). In addition, there is evidence that many drug promotions are not balanced or accurate. Sidney M. Wolfe, MD, *Direct-To-Consumer Advertising – Education or Emotion Promotion?* 346 N. Eng.



J. Med. 524, 526 (2002)(suggesting that "confusion arises when commercially driven promotional information is represented as educational.")

An FDA survey found that when patients asked their doctor about a drug, 48% received a prescription for that medication. Kathryn J. Aikin, PhD, FDA, *Direct-to-Consumer Advertising of Prescription Drugs: Preliminary Patient Survey Results* (Apr. 18, 2002), *available at* http://www.fda.gov/cder/ddmac/DTCnational2002a/sld040.htm. Moreover, for patients who asked about a specific brand, 69% received a script compared to 41% of those who asked about more general treatment.

In 2001, pharmaceutical companies spent $4.7 billion on physician detailing (the term of art for promotion of drugs to physicians) and over $2 billion on educational events aimed at physicians. Findlay, *supra*. Manufacturers also provided physicians with $10 billion worth of free samples to give patients and spent $2.8 billion direct-to-consumer marketing. *Id.* PhRMA keenly appreciates the fact that prior authorization may cause doctors to choose one drug over another, causing a potential of loss of sales for a drug that requires prior authorization yet is not clinically superior to one that does not require prior authorization. But harm to a patient would only occur if his or her physician refused to prescribe medically necessary drugs.

*Amici* believe the answer is to educate physicians, the public and administrators of the appropriateness of particular drugs for particular medical problems and the need to have a good system in place -- not prohibit a State from using its Medicaid prior authorization program to achieve savings for all its residents.

## CONCLUSION

Maine's attempt to expand access to medically necessary drugs to all of its residents by using its prior authorization authority in Medicaid does not on its face conflict with the Medicaid program. Maine has continually attempted to

broaden, not diminish, access to prescription drugs for its residents. The First Circuit's decision on the question of Medicaid preemption should be affirmed, and Maine Rx should be implemented.

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